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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,261	07/30/2003	Syed F. A. Hossainy	50623.276	8699

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EXAMINER

ROSENTHAL, CASEY S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/630,261

Applicant(s)

HOSSAINY ET AL.

Examiner

Casey Rosenthal

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.



### **DETAILED ACTION**

1. Receipt is acknowledged of applicant's Request to Resend Previous Nonpublication Request filed 7/19/2004 and Information Disclosure Statement filed 9/15/2003.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 3-7 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claims 3 and 14 recite the limitations "block A" in line 1 of the claims and "block B" in line 2 of the claims. There is insufficient antecedent basis for these limitations in the claims.
5. Claims 4 and 15 recite the limitations "block B" in line 1 of the claims and "block A" in line 2 of the claims. There is insufficient antecedent basis for these limitations in the claims.
6. Claims 5 and 16 recite the limitation "biological moiety" in line 1 of the claims. There is insufficient antecedent basis for this limitation in the claims.
7. Claims 6 and 17 recite the limitation "poly(ethylene glycol)" in line 2 of the claims. There is insufficient antecedent basis for this limitation in the claims.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-10 and 12-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldstein et al. (USPN 6,143,037).

10. Goldstein et al. disclose compositions for coating medical devices comprising pharmaceutical agents and block copolymers and methods of making thereof (abstract; column 1). Goldstein et al. also disclose various polymers including ethylene oxide, propylene oxide, polyalkylene glycols such as polyethylene glycol, and poly( $\epsilon$ -caprolactone) (column 14, lines 30-34; column 28, lines 50-52). More specifically, Goldstein et al. disclose copolymer blocks of ABA and BAB with specific examples being poly( $\epsilon$ -caprolactone)-block-poly(ethylene oxide)-block-poly( $\epsilon$ -caprolactone) and poly(ethylene oxide)-block-poly( $\epsilon$ -caprolactone)-block-poly(ethylene oxide) (column 28, lines 56-60; table 1). Goldstein et al. also disclose stents as a suitable coated medical device (column 31, lines 37) as well as various methods of applying the coating to the medical device (column 25, line 54 – column 31, line 24). Even though the reference is silent to one of the moieties producing a biological response and the other moiety provides a structural functionality, it is the position of the examiner that these properties are dependant upon the moieties themselves. The reference clearly discloses the block copolymers of claims 5-8 and 16-19 of the instant application as mentioned above in the

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rejection, therefore the composition is expected to have the same physiochemical properties as well as the same effect as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by Goldstein et al. anticipates the compositions enumerated in the instant claim set. These disclosures render the claims anticipated.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al. in view of Pinchuk et al. (US 2002/0107330 A1).

14. Goldstein et al. include the elements discussed above in paragraphs 8-10 of the rejection. However, Goldstein et al. does not disclose diazenium diolate. Pinchuk et al. includes diazenium diolate (paragraphs 0103, 0120 and 0124). In Goldstein et al. it

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would have been obvious to someone skilled in the art to include diazenium diolate as suggested by Pinchuk et al. in order to treat restenosis in a patient. The expected result would be a coated medical device capable of treating a patient in need thereof with a sustained release dosage of diazenium diolate.

15. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al. in view of Taylor et al. (WO 97/16133).

16. Goldstein et al. include the elements discussed above in paragraphs 8-10 of the rejection. However, Goldstein et al. does not disclose phosphoryl choline or polyaspirin. Taylor et al. includes phosphoryl choline (abstract). In Goldstein et al. it would have been obvious to someone skilled in the art to include phosphoryl choline as suggested by Taylor et al. in order to minimize unfavorable interactions such as thrombosis in a patient (page 6, line 11 – page 7, line 1). The expected result would be a decrease in the chances that a patient implanted with a coated stent would develop thrombosis.

### ***Conclusion***

17. All claims have been rejected; no claims are allowed.

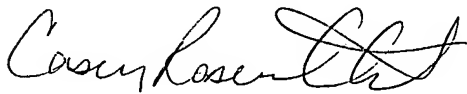
### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Rosenthal whose telephone number is 571-272-6097. The examiner can normally be reached on M-F from 8:00 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Casey Rosenthal  
Examiner  
Art Unit 1615



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